

Controlled Medical Device - Resin-based Dental Restorative Material

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[Product description]

[Intended purpose]

This product is intended to be used for restoration of intraoral cavities and chipped / damaged teeth, except for pulp. It is also intended to be used for repairing artificial crowns.

[Indications]

- Direct anterior and posterior restoration (excluding root canal filling)

[Intended users]

Dentist (Educated dental professionals who have theoretical and practical knowledge on usage of dental products.)
Patient target group: all patients requiring dental treatment, unless the patient’s condition like a known allergy limits the use.

[Clinical Benefit]

Repair a patient's teeth and artificial crowns by applying to intraoral cavities and chipped / damaged teeth.

[Contraindications and Prohibitions]

- DO NOT USE THIS PRODUCT ON PATIENTS WHO HAVE A HISTORY OF ALLERGIES SUCH AS IRRITATION TO THIS PRODUCT OR METHACRYLIC ACID AND SIMILAR ACIDS OR METHACRYLATE MONOMER.
- DO NOT REUSE NEEDLE TIPS.

[Shape, Composition and Description]

This product consists of the following items and contains the ingredients below:

Type	State	Components	Inorganic Filler Content
Universal	Paste	methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: average particle diameter <20μm), pigments, etc.	Approximately 81wt%
Universal St	Paste	methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: average particle diameter <20μm), pigments, etc.	Approximately 81wt%
Flow	Paste	methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: average particle diameter <20μm), pigments, etc.	Approximately 70wt%
Flow St	Paste	methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: average particle diameter <20μm), pigments, etc.	Approximately 70wt%
Low Flow	Paste	methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: average particle diameter <20μm), pigments, etc.	Approximately 71wt%
Low Flow St	Paste	methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: average particle diameter <20μm), pigments, etc.	Approximately 71wt%

Universal, Universal St, Flow and Low Flow: 1 shade (Basic)

Flow St and Low Flow St: 3 shade (Basic, White, Dark)Accessory: needle tips

Principles: This material is Resin-based Dental Restorative Material and is cured by visible light.

[Product Specifications]

Test method: ISO 4049

This material is applicable for the restoration of occlusal surfaces. It is polymerized and cured by visible light energy irradiation.

Items	Specification
Depth of Cure	1.5 mm or more
X-ray contrast	Positive

[Instructions for Use]

[Materials for use in combination with this product]

Dental Adhesive: e.g. “TMR-AQUA BOND 0” or “iGOS-BOND”

[Dental Curing Lights]

(1) Halogen Lamp

Dental curing light which uses halogen lamps as a light source, and which emits an effective wavelength of 400-515 nm, with a light intensity of 400 mW/cm² or more.

(2) LED Curing-Light

Dental curing light with blue LED as a light source; the peak of its emission spectrum is at 450-480 nm and it emits an effective wavelength of 400-515 nm. The light intensity is 1000 mW/cm² or more.

[Curing time and Depth of Cure]

The curing time and the depth of cure are as given in the following table.

The curing time needs to be adjusted depending on the amount of light and the wavelength of the light. When using this product under clinical conditions, please refer to the manual provided with the device you are using for information on appropriate light intensities for curing. Also, please refer to the following table and confirm the curing time and the depth of cure depending on your curing unit before using this product for clinical cases:

Curing Time and Depth of Cure

Dental light curing unit (Light Intensity) *1)	Curing Time	Shade and Depth of Cure
		Basic
Halogen	20 sec. or more	1.5 mm or more
LED with a light intensity of 1000 mW/cm² or more.	10 sec. or more *2)	
LED with a light intensity of 2400 mW/cm² or more.	4 sec. or more	

*1) Effective wavelength range should be 400-515 nm.

*2) A 20 sec. curing time is recommenced when using LED curing lights which emit an effective wavelength of 400-515nm with a light intensity that is less than 1000 mW/cm².

[Instructions]

(1) Anterior and Posterior Restoration

① Cleaning the tooth surface

Remove plaque and clean the surface of the tooth where restoration is needed.

② Cavity Preparation

Remove dental caries and create a cavity in accordance with normal practice.

③ Exclusion of moisture and pulp protection

To prevent contamination with blood and saliva, exclude moisture with a rubber dam. If cavity preparation is to be done significantly near to a dental pulp exposure area, perform the pulp capping procedure in accordance with normal practice.

④ Bonding treatment

Perform bonding treatment with a dental adhesive for coronal dentine, following the instructions.

⑤ Filling and curing

Fill this product into the cavity and light cure in accordance with the “Curing Time and Depth of Cure”. In cases where a cavity is deep, refer to the “Curing Time and Depth of Cure” and repeat the filling and curing steps.

Please note the following points as necessary.

- Check Shade Technical Guide as necessary.

⑥ Corrections and polishing

After curing, correct the shape in accordance with normal practice and polish with a silicone point or similar materials.

Prior to use, carefully read the instruction manual.

(2) Repairing Crown Restriction and Fractured Composite Resin

① Preparing the surface and coupling treatment by silane

Make the restoration surface rough with diamond points or similar materials and create a bevel at the margin area if needed.
Then prepare the restoration area following the instructions for primer and bonding.

② Concealing Shade

When a concealing shade is needed, apply opaquer thinly and cure following the instructions for the opaquer.

③ Filling and curing

Take out this product and fill in the cavity or build-up, then cure with a curing light.

- Check Shade Technical Guide as necessary.

④ Finishing and polishing

After curing, correct the shape in accordance with normal practice and polish with a silicone point or similar materials.

[N.B.: Technical Directions and Points for Attention]

- ① When using Flow and Flow St, remove the syringe cap and tightly attach a needle tip.
- ② Curing time needs to be adjusted depending on the amount of light and the wavelength of the curing unit. When using this product under clinical conditions, refer to the manual provided with the device you are using for information on appropriate light intensities for curing. Also, refer to the above table and confirm the curing time and the depth of cure depending on your curing unit before using this product for clinical cases.
- ③ Do not use surgical cotton wool which contains too much alcohol to remove this product from a needle tip or syringe. This causes alcohol to enter from the tip, and the material inside the syringe will be diluted; proper performance may not be exhibited. Squeeze out excess alcohol from the surgical cotton wool before using it.
- ④ Refer to the “Curing Time and Depth of Cure” and confirm the curing time and the depth of cure depending on your curing unit before using this product.
- ⑤ In cases where a cavity is deep, refer to the “Curing Time and Depth of Cure” and repeat the filling and curing steps.
- ⑥ Close the cap promptly and tightly after product collection. When using the Universal type, half-turn the handle counter-clockwise to release residual pressure.
- ⑦ Since this product is cured by ambient light, it should be protected by a shade cover or used up quickly when placed on a pallet or mixing paper.
- ⑧ Do not mix this product with other products, in order to prevent quality degradation of the material properties.
- ⑨ When using Flow and Flow St, be careful to prevent air bubbles from being entrapped in the material, as this can easily happen.
- ⑩ If this product is stored in a refrigerator, leave it at room temperature for several minutes before using it in order to prepare for use.
- ⑪ The depth of cure is affected by the irradiation capacity of the light curing unit; regular maintenance, such as cleaning and replacing lamps, is needed.
- ⑫ Since the handling time of this product will be shortened by the use of a shadowless lamp, turning the lamp off or reducing its light emission as required is necessary during filling and shaping.
- ⑬ If Universal and Universal St have not been used for a long time, tap the surface of the material to adjust the viscosity before use, since the material in the tip of the syringe might be hardened due to thixotropy.

[Precautions]

- ① This product is a combustible solid. Do not use or leave it in proximity to fire.
- ② Wear safety goggles to protect the eyes and do not look directly at the curing light during curing.
- ③ When polishing cured materials, use a suction device and anti-dust mask as approved by your local public safety agency in order to avoid inhaling dust.
- ④ If cavity preparation is to be done significantly near to dental pulp exposure area, perform pulp capping procedure in accordance with normal practice.
- ⑤ Do not use eugenol or related products as it may hinder curing and bonding.
- ⑥ Handle carefully to prevent accidental ingestion of this material.
- ⑦ To prevent cross infection, do not use the same needle tip and applicator for different patients and do not reuse them.
- ⑧ When using Flow or Low Flow, cover the whole syringe with plastic wrapping materials to ensure that it does not come into contact with saliva, blood, etc., to prevent cross-infection.
- ⑨ Do not use this product in combination with other products.
- ⑩ Do not use this product outside the scope of recommended indications, effects or efficacy.
- ⑪ Only adequately certified personnel should handle this product.
- ⑫ Dispose of this product as a medical waste to prevent infection.

[Important Basic Cautions]

- ① Stop using this product immediately if any signs of allergy, such as irritation or rash, appear in patients. If symptoms persist, seek medical advice.
- ② Operators must discontinue use if any signs of irritation or rash appear. If symptoms persist, seek medical advice.
- ③ In order to avoid irritation, pay attention to prevent the adhesion of this product to oral soft tissue or to the skin. In case of oral soft tissue contact or skin contact, wipe with an alcohol-soaked cotton swab, and wash with plenty of water. In case of eye contact,

immediately rinse out the eye with plenty of running water, and consult a physician.

- ④ Wear plastic gloves and safety goggles to prevent the adhesion of this product to the skin. In case of skin contact, wipe with an alcohol-soaked cotton swab, and wash with plenty of running water. In case of eye contact, immediately rinse out the eye with plenty of running water, and consult a physician.

[Other Cautions]

The restoration area may be stained and plaque-adherent depending on patients’ dietary habits. Advise on daily oral cleaning.

[Handling and Storage]

- ① This product must be stored at a room temperature of 1-30°C.
- ② Do not store large quantities of product in the same storage area.
- ③ Equip work and storage areas with fire extinguishers.
- ④ Keep out of reach of personnel other than dental staff.

[Note]

If a serious incident attributable to this product occurs, report it to the manufacturer shown below and the regulatory authorities of the country in which the user/patient resides.

[Expiry Date]

- ① This product must be used before the expiry date* printed on the package.
- ② The expiry date printed on the package is based on the authentication by YAMAKIN.
- ③ The expiry date printed on the package refers to use expiry date.
*(e.g.; EXP YYYY-MM indicates YYYY ‘year’/MM ‘month’ (last day) as the expiry date)

[Package]

[Single Package]

- Universal Basic 4.0 g (2 ml)
- Universal St Basic 4.0 g (2 ml)
- Flow Basic 2.8g (1.5ml)
Accessory: needle tips x 10 pcs
- Flow St Basic 2.8g (1.5ml)
Accessory: needle tips x 10 pcs
- Low Flow Basic 2.8g (1.5ml)
Accessory: needle tips x 10 pcs
- Low Flow St Basic 2.8g (1.5ml)
Accessory: needle tips x 10 pcs

[Set Package]

- 3 pcs Pack (Universal, Basic)
- 3 pcs Pack (Universal St, Basic)
- 3 pcs Pack (Flow, Basic)
- 3 pcs Pack (Flow St, Basic)
- 3 pcs Pack (Low Flow, Basic)
- 3 pcs Pack (Low Flow St, Basic)

[Accessory/ Single Item]

- Needle tips: x 20 pcs.

 **YAMAKIN**

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